510(k) Summary

In accordance with 21 CFR 807.92(c) the following summary of information is provided:

Date Prepared:	September 8, 2011
Submitter:	Medicis Technologies Corporation 11818 North Creek Parkway North Bothell, WA 98011 USA
Contact Person:	Michael A. Hoffman, MPH Vice President - Regulatory Affairs and Quality Systems Medicis Technologies Corp. 11818 North Creek Parkway North Bothell, WA 98011 USA
Telephone:	425.420.2135
Facsimile:	425.420.2335
FR Number:	21 CFR 878.4590
Product Code:	OHV
Classification Name	Focused Ultrasound Stimulator System for Aesthetic Use
Common Name:	Focused Ultrasound Stimulator System for Aesthetic Use
Trade Name:	LipoSonix® system Model 2
Regulatory Class:	Class II
Classification Advisory Committee:	Division of General, Restorative and Neurological Devices; General Surgery Devices Branch
Special Controls:	Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use (July 20, 2011)
Predicate Device(s):	K100874, LipoSonix® system Model 1
Intended Use/Indications for Use:	The *LipoSonix* system delivers high intensity focused ultrasound (HIFU) energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. The *LipoSonix* system is specifically indicated for non-invasive waist circumference reduction.

Contraindications: A patient is ineligible for treatment with the *LipoSonix* system if any of the following criteria are met:

- The patient is a female who is pregnant, may be pregnant, or is lactating. Female patients of child bearing age should have a negative pregnancy test before being treated with the *LipoSonix* system.
- The patient has less than 1.0 cm of adipose tissue thickness beyond the selected treatment focal depth in the area to be treated.
- Hernia in the area to be treated.

Device Description: The *LipoSonix* system is a cart-based medical device intended for non-invasive disruption of subcutaneous adipose tissue (SAT) by employing ultrasound energy. The system consists of a cart, a detachable handpiece and a user interface display in one unit.

Technology: The *LipoSonix* system accomplishes its intended use through the use of precisely targeted high intensity focused ultrasound energy that produces a thermal cellular disruption in the subcutaneous adipose tissue (soft tissue). This thermal energy also causes collagen to contract. Thus creating a dual tissue response. The destroyed adipose tissue is subsequently cleared via an inflammatory response by macrophages that transported the destroyed cells and their contents to the liver via the lymphatic system.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The system has been found to conform to the system essential specifications, thermal, electrical, electromagnetic and mechanical safety, and has been found to conform to FDA consensus, medical device safety standards and international harmonized standards.

The following risks as identified in the FDA special control guidance document entitled, "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use" have been addressed.

- Thermal Injury from Focused Ultrasound Exposure (Thermal Damage)
- Mechanical Injury from Focused Ultrasound Exposure
- (Cavitation or other Mechanical Damage)
- Ocular Injury
- Electrical Shock
- Inflammation/Foreign Body Response
- Use Error

Performance Data: The *LipoSonix* system was evaluated in a multicenter, randomized study. Treatment with the *LipoSonix* system was shown to be superior to a sham control in reducing waist circumference, meeting the pre-specified primary endpoint of the study. The 59 J/cm^2 treatment group demonstrated a 1.01 cm greater waist circumference reduction as compared to sham. The least square (LS) mean change from baseline to 12 weeks of the waist circumference in the same 59 J/cm^2 group was -2.44 cm. On average, the mean change in waist circumference of approximately 2.55 cm (1 inch) compared to baseline that was demonstrated in the 59 J/cm^2 treatment group. This could equal one dress or pant size.

The safety of treatment with the *LipoSonix* system was assessed through 24 weeks post-treatment. The AEs resulting from treatment with the *LipoSonix* system during this study were mostly mild, short-lived in duration, and resolved without incident. There were no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) related to treatment with the investigational device.

Substantial Equivalence: The *LipoSonix* system is substantially equivalent to the *LipoSonix* system Model1 (K100874) device.

The *LipoSonix* system Model 2 has the same intended use as the Model 1 system, namely performing a non-invasive treatment to achieve a desired aesthetic effect. Both systems use the same technological principles, namely HIFU, to thermally disrupt soft tissues which result in the aesthetic affect. The mechanism of action for both devices is essentially the same as well. Disrupted soft tissue is removed by normal healing processes of the body resulting in an aesthetic affect. Both devices can deliver more than one energy dose.

Therefore, the *LipoSonix* system Model 2 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 20 2011

Medicis Technologies Corporation
% Michael A. Hoffman, MPH
Vice President – Regulatory Affairs
and Quality Systems
11818 North Creek Parkway North
Bothell, Washington 98011

Re: K112626
Trade/Device Name: LipoSonix® System Model 2
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused ultrasound stimulator system for aesthetic use
Regulatory Class: Class II
Product Code: OHV
Dated: October 04, 2011
Received: October 04, 2011

Dear Mr. Hoffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This Submission

Device Name: LipoSonix® system Model 2

Indications For Use:

The *LipoSonix* system delivers high intensity focused ultrasound (HIFU) energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect.

The *LipoSonix* system is specifically indicated for non-invasive waist circumference reduction.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112626